

**REMARKS/ARGUMENTS**

Reconsideration of the above-identified application is respectfully requested.

In the Final Office Action dated January 29, 2007, claims 1 and 3-29 are pending.

Claims 1 and 3-14 are elected for further examination and are rejected.

Claims 1 and 3-14 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

Claims 1, 3-12 and 14 are rejected under 35 U.S.C. § 102(b) as being anticipated by Zhong et al.

Claims 1, 12 and 14 are rejected under 35 U.S.C. § 102(a) as being anticipated by GenBank Accession Nos. AL929535.

Claims 1, 12 and 14 are rejected under 35 U.S.C. § 102(a) as being anticipated by GenBank Accession Nos. AC139623.

Claim 1 is rejected under 35 U.S.C. § 102(a) as being anticipated by GenBank Accession No. BX240588.

In response to the rejections, Applicants have amended claims 1, 5-7, 10 and 11 and canceled claims 3, 4, 8 and 9. In particular, claim 1 is amended to incorporate the limitation of 3-4, which is permissive under final rejections. No new matter has been introduced.

Applicants respectfully submit that the amendments have overcome the rejections for the reasons set forth below:

**Rejections Under 35 U.S.C. § 112, First Paragraph**

Claims 1 and 3-14 are rejected under 35 U.S.C. § 112, first paragraph, as failing

to comply with the written description requirement for reasons stated on pages 3-5 of the Office Action. Specifically, the Office Action alleges that Applicants fail to provide adequate written description for “an isolated polynucleotide comprising a liver-specific expression control sequence that modulates expression of vertebrate liver fatty acid binding protein (L-FABP).” The Office Action also alleges that Applicants fail to provide an indication of how the sequences of SEQ ID NOS:1-3 are representative of variants having at least 80% homology to these sequences. The Office Action further alleges that the addition of the phrase “from a fish” and “a functional variant” do not provide a sufficiently limited definition of the claimed polynucleotide.

In response to the rejection, Applicants have amended claim 1 to recite “an isolated polynucleotide comprising a liver-specific expression control sequence from a zebrafish which comprises binding sites for HFH(1) having the nucleotide sequence of SEQ ID NO:4, HFH(2) having the nucleotide sequence of SEQ ID NO:5, HNF-1 $\alpha$  having the nucleotide sequence of SEQ ID NO:6, and HNF-3 $\beta$  having the nucleotide sequence of SEQ ID NO:7, and modulates expression of a vertebrate liver fatty acid binding protein (L-FABP),” which incorporates the limitations of claims 3-4, and is fully supported by the specification. Applicants have also amended claims 6, 10 and 11 to delete the phrase “a functional variant.”

Applicants respectfully submit that the amendments obviate the grounds for the rejection. Withdrawal of the rejection to claims 1, 5-7, and 10-14 under 35 U.S.C. § 112, first paragraph, is respectfully requested. Claims 3, 4, 8 and 9 have been canceled. Rejection to these claims is now moot.

**Rejections Under 35 U.S.C. § 102**

Claims 1, 3-12 and 14 are rejected under 35 U.S.C. § 102(b) over Zhong et al. for reasons stated on pages 5-9 of the Office Action. Specifically, the Office Action alleges that Zhong inherently contains a liver-specific expression control sequence.

For anticipation under 35 U.S.C. §102, the reference “must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present.” (MPEP §706.02, IV. Distinction between 35 U.S.C. 102 and 103, page 700-21). The Federal Circuit has held that prior art is anticipatory only if every element of the claimed invention is disclosed in a single item of prior art in the form literally defined in the claim. *See e.g., Jamesbury Corp. v. Litton Indus. Products*, 756 F.2d 1556, (Fed. Cir. 1985); *See also Atlas Powder Co. v. DuPont*, 750 F.2d 1569, (Fed. Cir. 1984); *American Hospital Suppl v. Travenol Labs*, 745 F.2d 1 (Fed. Cir. 1984).

Zhong describes the construction of a zebrafish genomic library from zebrafish embryos in yeast artificial chromosomes. Zhong does not disclose “an isolated polynucleotide comprising a liver-specific expression control sequence from a zebrafish, wherein said expression control sequence comprises the binding sites for HFH(1) having the nucleotide sequence of SEQ ID NO:4, HFH(2) having the nucleotide sequence of SEQ ID NO:5, HNF-1 $\alpha$  having the nucleotide sequence of SEQ ID NO:6, and HNF-3 $\beta$  having the nucleotide sequence of SEQ ID NO:7, and modulates expression of a vertebrate liver fatty acid binding protein (L-FABP),” as recited in amended claim 1.

The Examiner, in response to applicants’ arguments filed 8/15/2006, argues that “Zhong anticipates claim 1 because “[c]laim 1 is a broad claim that does not recite a

specific sequence for the isolated polynucleotide comprising a liver-expression control sequence.” See Final Office Action at 7.

Applicants respectfully submit that claim 1, as amended, recites specific sequences (*i.e.*, SEQ ID NOS: 4-7) in the claimed liver-specific expression control sequence which must contain the binding sites for HFH(1), HFH(2), HNF-1 $\alpha$ , and HNF-3 $\beta$ . As demonstrated in Figures 11-13 and the corresponding text in the specification, the oligonucleotides corresponding to the binding sites for HFH(1), HFH(2), HNF-1 $\alpha$ , and HNF-3 $\beta$  are not connected to each other. Since Zhong provides the zebrafish library in many different clones with no disclosure as to which clone(s) contain which specific sequence(s), there is no teaching or indication that all of the oligonucleotides corresponding to the bindings sites for HFH(1), HFH(2), HNF-1 $\alpha$ , and HNF-3 $\beta$  can be found in one clone of Zhong’s zebrafish library, which can be found by any ordinary skill in the art, Applicants’ claimed invention is not inherently anticipated by Zhong.

Applicants would like to further remind the Examiner that it is a requirement for the “inherent anticipation” to apply only when the characteristic of the claimed invention is “itself sufficiently described and enabled” in the prior art, as admitted by the Examiner in her Final Office Action, See Final Action at 7, where she quoted *Toro Co. v. Deere Co.*, 355 F.3d 1313, 1320 (Fed. Cir. 2004). The Examiner has not established that Zhong has sufficiently described and enabled the claimed polynucleotide.

Moreover, since Zhong simply discloses the generation of a genomic library for zebrafish, and does not provide the sequences of all clones, nor does it provide any guidance as to which clones might contain the claimed sequence, or where the claimed sequence might be located in these clones, the claimed sequences cannot be “at once

envisaged” from Zhong’s disclosure, as required by MPEP for anticipation of a species from a general formula.

Accordingly, claim 1 is not anticipated by Zhong. Claims 5-7 and 10-14 are also patentable over Zhong because they depend from claim 1 and recite additional patentable subject matter. Withdrawal of the rejection to claims 1, 5-7, and 10-14 under 35 U.S.C. § 102(b) over Zhong is respectfully requested. Claims 3, 4, 8 and 9 have been canceled. Rejection to these claims is now moot.

Claims 1, 12 and 14 are rejected under 35 U.S.C. § 102(a) over GenBank Accession Nos. AL929535 and AC139623. Claim 1 is rejected under 35 U.S.C. § 102(a) over GenBank Accession No. BX240588.

GenBank Accession No. AL929535 is a 162435 base pair zebrafish DNA sequence. GenBank Accession No. AC139623 is a 203371 bp zebrafish DNA sequence. GenBank Accession No. BX240588 is a 738 bp zebrafish DNA sequence. These sequences do not specifically disclose “an isolated polynucleotide comprising a liver-specific expression control sequence from a zebrafish which comprises the binding sites for HFH(1) having the nucleotide sequence of SEQ ID NO:4, HFH(2) having the nucleotide sequence of SEQ ID NO:5, HNF-1 $\alpha$  having the nucleotide sequence of SEQ ID NO:6, and HNF-3 $\beta$  having the nucleotide sequence of SEQ ID NO:7,” as recited in the amended claim 1, nor do they provide any guidance on how to locate such sequences. Therefore, claim 1 is not anticipated by GenBank Accession Nos. AL929535, AC139623 and BX240588. Claims 12 and 14 are also patentable over GenBank Accession Nos. AL929535 and AC139623 because they depend from claim 1 and recite additional patentable subject matter. Withdrawal of the rejections to claims 1, 12, and 14 under 35

U.S.C. § 102(b) over GenBank Accession Nos. AL929535, AC139623 and BX240588 is respectfully requested.

Finally, the Office Action repeatedly alleges that the issues in *In re Rijckert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993) is not applicable to the merit of the instant case, since the issues of *In re Rijckaert* dealt with obviousness and a claimed relationship between three variables to time expansion/compression for magnetic record carrier. Applicants respectfully disagree.

First, the legal standard for determining inherency under 35 U.S.C. 103 or 102 is the same. (See e.g., MPEP 2112, "A rejection under 35 U.S.C. 102/103 can be made when the prior art product seems to be identical except that the prior art is silent as to an inherent characteristic"). Therefore, *In re Rijckaert* applies to the instant case.

Second, *In re Rijckaert* was cited not for its facts but for the principles it used to determine inherency. In *In re Rijckaert*, the court held that a claimed relationship between three variables to time expansion/compression for magnetic record carrier is not inherent from the prior art Awamoto because "Awamoto does not indicate that the relationship is well known in the art, nor does it suggest the claimed relationship." *Id* at 1533. In the instant case, the claims are directed to specific nucleotide sequences with a specific function. The cited prior art references do not disclose the specific sequences, nor do they suggest the claimed function.

Finally, the Federal Circuit has used principles similar to that of *In re Rijckaert* in other cases dealing with anticipation by inherency. For example, the court noted in *In re Oelrich*, 666 F.2d 578, (CCPA 1981) that "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the

thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' (see also, *In re Robertson*, 169 F.3d 743 (Fed. Cir. 1999) ). The court also noted that a prior art reference that discloses a genus still does not inherently disclose all species within that broad category but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1367 (Fed. Cir. 2004)

Taken together, Applicants respectfully submit that the principles illustrated in *In re Rijckaert*, *In re Oelrich*, and *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings* apply to the instant case, and that the claimed invention is not inherently anticipated by the cited prior art references.

In view of the foregoing remarks, favorable reconsideration of all pending claims is requested. Applicants respectfully submit that this application is in condition for allowance and request that a notice of allowance be issued. Should the Examiner believe that anything further is required to expedite the prosecution of this application or further clarify the issues, the Examiner is requested to contact Applicants' attorney at the telephone number listed below.

Respectfully submitted,

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